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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/155,642    10/02/98    LINDAHL

A    003300-506

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EXAMINER

WANG, S

ART UNIT

PAPER NUMBER

1617

DATE MAILED:

04/17/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

<b>Office Action Summary</b>	Application No. 09/155,642	Applicant(s) LINDAHL ET AL.	
	Examiner Shengjun Wang	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 February 2001.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 55-99 is/are pending in the application.
- 4a) Of the above claim(s) 59, 60, 80, 81, 83, 84, 95, 96, 98 and 99 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 55-59, 61-79, 82, 85-94 and 97 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 18) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. Claims 59, 60, 80-81, 83-84, 95-96 and 98-99 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 15 submitted February 12, 2001.

2. Applicant's election with traverse of species corticosteroid or steroid in Paper No. 15 is acknowledged. The traversal is on the ground(s) that the claimed invention is based on a specific, novel carrier system. This is not found persuasive because the compounds encompassed by the bioactive agent herein are so diversified, i.e., their chemical structure and biological properties are widely, and distinctly different. Further, search each and every compound as specified in the claims is seen to be an undue burden to the examiner.

The requirement is still deemed proper and is therefore made FINAL.

The claims have been examined insofar as they read on the elected species.

### ***Claim Rejections 35 U.S.C. § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 75, 77-79 and 86 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. The term "suitable" in claims 75 and 77 is a relative term that renders the claim indefinite. The term "suitable" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be

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reasonably apprised of the scope of the invention. Claim 75 is indefinite as to the form of the composition. Claims 77-79 are indefinite as to the active agent.

6. The term "low" in claim 86 is a relative term which renders the claim indefinite. The term "low" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The claim is indefinite as to the molecular weight of the branched chain aliphatic acids or alcohols.

*Claim Rejections 35 U.S.C. § 103*

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 55-58, 61-79, 82, 85-94 and 97 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamada et al. (U.S. Patent 5,362,497) in view of Wang et al. (U.S. Patent 4,299,828 of record), Copper (U.S. Patent 4,552,872 of record).

9. Yamada teach a transdermal therapeutic composition comprising pharmaceutical effective ingredient, e.g., corticosteroid, a water-soluble absorption enhancer, e.g., propylene glycol, (1-50%) and a fat soluble absorption enhancer comprising fatty alcohol, e.g., oleyl alcohol, (0.5-20%) and a lower alcohol ester of aliphatic carboxylic acid such as myristic acid or palmitic acid (1-50%). The typical lower alcohol is propanol. See column 2-4, particularly, column 3, line 16, 57-63, column 4, lines 5-6, 19, 41-52. The composition may be made into various forms by adding ingredients well known in the art such as bees-wax, lanolin glycerol

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fatty esters. See, particularly, column 5, line 38 bridging column 6, line 41. Yamada further teach that, for fat soluble active ingredient, the active ingredient was first mixture with the fatty alcohols followed by mixing with other ingredients. See, particularly, column 6, lines 59-68.

10. The primary reference does not teach expressly the particular formulation herein which has corticosteroid as the active ingredient, and comprising unsaturated alcohols, lower alcohol ester of fatty acid, wax and plasticizing oil with the particular percentage, or the particular form, stick, or the method of using the same.

11. However, Copper teach that unsaturated alcohol such as oleyl alcohol in combination with propylene glycol are particular useful in topical composition containing corticosteroids. More specifically, Copper teach a composition comprising 0.02-5% of corticosteroid, 15-99 % of propylene glycol and oleyl alcohol as vehicle for treatment of dermatological disorder. See, Column 7, lines 28-68, and column 8, lines 31-68, and column 14, composition III. Cooper also teaches the inclusion of a wax to impart the stiffness to the composition. See, column 10, lines 35-54. Wang et al. teaches a corticosteroid containing stick formulation comprising wax to provide body and stiffness. See, the abstract, column 3, lines 49-64 and column 4, lines 10-54.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to modify the composition of Yamada to make a corticosteroid containing topical composition employing oleyl alcohol as the fat soluble enhancer and propylene glycol as the water soluble enhancer with the particular amounts claimed herein.

A person of ordinary skill in the art would have been motivated to modify the composition of Yamada to make a corticosteroid containing topical composition employing oleyl alcohol as the fat soluble enhancer and propylene glycol as the water soluble enhancer with the

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particular amounts claimed herein because both are known to be useful to enhance the absorption of the active ingredients and the amounts of such ingredients herein is encompassed by scope taught by the prior art. The employment of wax and plasticizer to render the final product certain properties is seen to be within the skill of artisan. The optimization of the amounts of each known ingredient in the composition is considered within the skill of artisan, absent evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (703) 308-4554. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

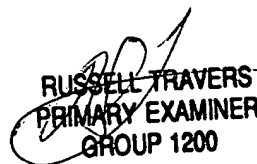
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



Shengjun Wang

AU 1617

April 13, 2001



RUSSELL TRAVERS  
PRIMARY EXAMINER  
GROUP 1200